

Remarks

The above-identified application has been carefully reviewed in light of the Examiner's office action mailed on March 3, 2008. Submitted herewith is a Request for Extension of Time, and required fee, extending the period for responding to the Office Action to and including July 3, 2008

Without conceding the correctness of any of the Examiner's rejections, the present claims have been amended to facilitate prosecution of the above-identified application and to obtain an early allowance. Applicant expressly reserves the right to seek patent protection for the original and previously pending claims and all other claims supported by the above-identified application in one or more later filed, related patent applications.

Specifically, the claims, for example, claims 33, 55 and 61, have been amended to delete reference to a woman "prone to experiencing hot flashes associated with menopause", which language was questioned by the Examiner as not being enabled. Also, claim 67 has been canceled, without prejudice and claims 68-70 have been amended to delete reference to the placing step being "effective to prevent a (the) hot flash associated with menopause from spreading through the body of the woman", which the Examiner asserts has not been enabled. In addition, claims 55 and 61 have been amended to refer, in the alternative, to a women who "is anticipating experiencing a hot flash associated with menopause". This latter amendment is fully supported and enabled by the present specification, for example, at page 9, lines 7-22; page 17, lines 4-12, and page 17, lines 21-27.

The Examiner contends that the enabling disclosure of the above-identified application is limited to placing a cooling device at the site of onset of the hot flashes, i.e., hot flashes must happen first before treatment by applying the cooling device. Applicant vigorously disagrees.

The above-identified application includes disclosures of placing the cooling device on the upper back of a woman without stating that the upper back of the woman is the site of onset or origin of the hot flash. See the present specification, for example, at page 4, lines 5-13; page 17, lines 4-12 and 21-27; page 18, lines 12-18; and Fig. 5 and the description thereof in the specification.

Thus, although the origin site of the hot flash may be one factor influencing the placement of the cooling device, it is clear from the present specification that placing the cooling device on the upper back of the woman, independent of the origin site of the hot flash or anticipated hot flash associated with menopause, is fully supported and enabled by the present specification and the above-identified application.

In view of the amendments to the claims and the above stated remarks, applicant submits that the present claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 68-70 are enabled by the present specification and the above-identified application, and satisfy the requirements of 35 U.S.C. 112, first paragraph. Therefore, applicant respectfully requests the Examiner to withdraw the rejection of the present claims based on this statutory provision.

Claims 33, 41, 44, 45, 61, 69 and 70 have been rejected under 35 U.S.C. 103(a) as being unpatentable by the "BeKool"

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product for treating hot flashes by Kobayashi Healthcare, Inc., and was presented as: "Product Concept Test" (PCT) by itself or in view of the article by "Pharmacy Key" (Pharmacy Key). Claims 35, 36, 38, 55, 57-59, 62-65, 65, 67 and 68 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the "BeKool" product for treating hot flashes in view of any of JP 2002119529 (JP '529) or U.S. Patent 6,224,899 (U.S. '899). Applicant vigorously traverses each of these rejections.

The present invention is directed to methods of treating hot flashes associated with menopause in a woman.

Independent claim 33 defines embodiments of the invention which comprise providing a woman experiencing a hot flash associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause.

Independent claim 55 defines embodiments of the invention which comprise removing a cooling device from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman, and thereafter placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash associated with menopause or who is anticipating experiencing hot flashes associated with menopause, the cooling device comprising a water-containing gel.

Independent claim 61 defines embodiments of the invention which comprise removing a cooling device from a package having instructions to place the cooling device at a location on an

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upper back of a woman experiencing a hot flash associated with menopause or who is anticipating experiencing hot flashes associated with menopause, and placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash associated with menopause or who is anticipating experiencing a hot flash associated with menopause.

A hot flash associated with menopause, such as caused by hormonal changes associated with menopause in a woman, is often experienced as a wave-like warming sensation throughout a woman's body, for example, radiating from the front of the chest. This wave-like warming sensation can be highly unpleasant, even embarrassing due to a flushing of the face. Applicant, and applicant alone, has discovered that, by placing a cooling device specifically at a location on an upper back of a woman experiencing a hot flash or anticipating experiencing a hot flash, the hot flash can be successfully treated, for example, the wave-like warming sensation and the flushing of the face are significantly lessened in intensity.

Applicant has surprisingly and unexpectedly found that placing a cooling device at a location on the upper back, for example, at a region in proximity to the cervical and thoracic vertebrae, such as between the C3 vertebrae and the T6 vertebrae, of a woman who is experiencing a hot flash or who is anticipating experiencing a hot flash, for example, during the hot flash or in anticipation of a hot flash, that the hot flash is effectively and advantageously treated.

Further, and importantly the claimed methods allow a woman to easily and discreetly treat menopausal hot flashes at virtually any time, no matter where the woman is or what she is

doing. For example, application of the cooling device at a location on an upper back is very effective in reducing the hot flash symptoms, and, in addition, because the upper back is a discreet location of the body, advantageously facilitates privacy in that the cooling device located on the upper back can be discreetly concealed under clothing. Thus, the present methods very effectively treat menopausal hot flashes, and do so discretely, without embarrassing the woman. This surprising and unexpected combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to carry on with her normal activities, achieved in accordance with the present invention, gives the woman more comfort and more confidence during an especially difficult time in her life.

In support of the rejections under 35 U.S.C. 103(a), the Examiner states that "BeKool" is a cooling gel sheet used for treating hot flashes, and that the Product Concept Test (PCT) implies that the gel sheets have been in use for hot flashes before August 14, 2003, the date of the PCT.

The "BeKool" Hot Flash material or pamphlet relied on by the Examiner as the primary reference in both 35 U.S.C. 103(a) rejections is undated. The Examiner has provided no evidentiary basis, and applicant believes no such evidentiary basis exists, for the present rejections based on the cited "BeKool" Hot Flash material or pamphlet being prior art against the present claims, which claim the benefit of U.S. Provisional Application 60/563,237, filed April 16, 2004. In short, this "BeKool" Hot

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Flash material or pamphlet is not prior art against the present claims.

Applicant's attorney understands that applicant, Mary J. Champion, telephoned Examiner Ghali on March 31, 2008 to discuss the "BeKool" Hot Flash material (pamphlet) being cited by the Examiner against the present claims. Ms. Champion told the Examiner that she had evidence that the "BeKool" Hot Flash material being cited by the Examiner was not prior art against the above-identified application. The Examiner suggested that Ms. Champion present this evidence in the form of a Declaration/Affidavit.

In response to the Examiner's suggestion, submitted herewith is a DECLARATION OF MARY J. CHAMPION UNDER 37 CFR 1.132 (Champion Declaration) presenting evidence that the "BeKool" Hot Flash material (pamphlet) being cited by the Examiner is not prior art against the above-identified application.

A brief summary of the Champion Declaration is as follows. Ms. Champion conducted extensive research on the internet looking for perspective licensees of the present invention (Champion Declaration, paragraph 2). During the period after the filing of the above-noted provisional application on which the above-identified application is based, Ms. Champion noted that Kobayashi Healthcare, Inc. (Kobayashi) did sell/advertise cooling patches for fevers, migraines, sprains, arthritis, toothaches, heat discomfort, overexertion and overheating. However, the Kobayashi website did not show, mention or otherwise even suggest the cooling patches were, or even could be, used to treat hot flashes associated with menopause (Champion Declaration, paragraph 3).

Ms. Champion contacted Kobayashi to inquire about a possible interest in the present invention. She was informed that Kobayashi declined to sign a non-disclosure agreement with Ms. Champion. In the discussions in May, 2004, Kobayashi did not inform Ms. Champion that they were marketing/selling or even contemplating marketing/selling any product for treating hot flashes associated with menopause (Champion Declaration, paragraph 4).

Periodically through 2004 and the first half of 2005, Ms. Champion checked Kobayashi's website and confirmed that no showing or other disclosure was made on the website that the "Be Kool" product or any other Kobayashi product was, or even could be, used to treat hot flashes (Champion Declaration, paragraph 6). Further, during this time period, Ms. Champion did not see any advertising, packaging or other material for any "BeKool for Adults" product referring to hot flashes (Champion Declaration, paragraph 6).

Ms. Champion states that, based on her own research on the internet and since neither Kobayashi nor anyone else identified any cooling product to treat hot flashes associated with menopause, no cooling product from Kobayashi for the treatment of such hot flashes was marketed/sold before or during 2004 and during the first half of 2005 (Champion Declaration, paragraph 7).

In July, 2005, Ms. Champion first became aware of Kobayashi's new product, packaging and advertisement for "Be Kool Hot Flash" (Champion declaration, paragraph 8). Ms. Champion promptly contacted Kobayashi to discuss this development, and was provided with a power point presentation of

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an unpublished, half-completed Product Concept Test, which bears a date in 2003 (Champion Declaration, paragraph 8). Ms. Champion has no way of verifying if the Product Concept Test was conducted at all, let alone in 2003. This is particularly true since Kobayashi's product, "BeKool Hot Flash" was not marketed/sold until July, 2005. In addition, the Product Concept Test does not disclose the invention claimed in the present application (Champion Declaration, paragraph 8).

Ms. Champion states in her Declaration that on December 3, 2007, an office action in the above-identified application was mailed by the Examiner. In this office action, for the first time, the Examiner cited the "BeKool Hot Flash" material (pamphlet) against the claims of the above-identified application. Specifically, the "BeKool Hot Flash" material was described in an undated pamphlet, shown in Attachment C of the Champion Declaration, which was provided by the Examiner in Form PTO 892. A part of the pamphlet is similar to the product, packaging and advertisement for "BeKool Hot Flash" (Attachment B of the Champion Declaration) which is dated July, 2005. The only date on the "BeKool Hot Flash" material (pamphlet) received from the Patent and Trademark Office is 11/29/07. Thus, the earliest date that Ms. Champion is aware of that any portion of the pamphlet was published is July, 2005, well after the filing date of the above-noted provisional application (Champion Declaration, paragraph 9).

In view of the above, Ms. Champion declares that the "BeKool Hot Flash" material or pamphlet being relied on the Examiner to reject the claims in the above-identified application is not prior art against the present claims, each of

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which is fully supported by the above-noted provisional application, dated April 16, 2004 (Champion Declaration, paragraph 10).

Applicant's attorney has repeatedly asked the Examiner to provide evidence that the "BeKool Hot Flash" pamphlet being relied on by the Examiner is, in fact, prior art against the present invention. The Examiner has not provided any such evidence. Simply put, the Examiner has not provided any evidentiary basis that the "BeKool Hot Flash" material or pamphlet relied on by the Examiner is prior art against the present claims.

The Champion Declaration, discussed above, provides quite specific evidence that the "BeKool Hot Flash" material being relied on by the Examiner is not prior art against the present claims.

In view of the above, applicant submits that the only evidence presented in the above-identified application regarding the date or prior art status of the "BeKool Hot Flash" material or pamphlet being relied on by the Examiner is that such material is not prior art against the present claims. The Examiner has provided no evidentiary basis, and applicant submits that no evidentiary basis exists, that the "BeKool Hot Flash" material or pamphlet relied on by the Examiner is, in fact, prior art against the present claims. To the contrary, the only evidence is that the "BeKool Hot Flash" material or pamphlet being relied on by the Examiner as the primary reference in both rejections under 35 U.S.C. 103(a) is not prior art against the present claims.

Since the "BeKool Hot Flash" material or pamphlet relied on by the Examiner is the primary reference against the present claims, and since such material is not prior art against the present claims, applicant submits that each of the rejections set forth above with regard to the present claims, is moot, and respectfully requests that both rejections be withdrawn.

Moreover, the Product Concept Test (PCT) does not disclose, teach, imply or suggest the present invention. For example, the PCT does not disclose, teach, imply or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing a woman experiencing a hot flash associated with menopause with at least one cooling device in a package having instructions to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman to thereby treat the hot flash associated with menopause, as recited in claim 33.

Further, the PCT does not disclose, teach, imply or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises removing a cooling device, comprising a water-containing gel, from a package having instructions for treating hot flashes associated with menopause using the cooling device on an upper back of a woman; and, thereafter placing the cooling device at a location on an upper back of a woman who is experiencing a hot flash or who is anticipating experiencing a hot flash, as recited in claim 55.

In addition, the PCT does not disclose, teach, imply or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of

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removing a cooling device from a package having instructions to place the cooling device at a location on an upper back of a woman experiencing a hot flash associated with menopause who is anticipating experiencing a hot flash associated with menopause, and placing the cooling device removed from the package at a location on an upper back of a woman who is experiencing a hot flash or who is anticipating experiencing a hot flash, as recited in claim 61.

The PCT does not disclose, teach, imply or even suggest instructing a user to place the cooling device on any specific site, let alone at a location on the upper back of the woman, as recited in the present claims. While the Examiner states that the PCT implies that a product was used to treat hot flashes before August 14, 2003, a careful reading of the PCT shows that the PCT does not so imply.

In particular, the PCT is based on consumer opinion interviews, and not on actual use of any product for any specific purpose. The PCT does not include any mention of any location on the body of a woman, let alone the upper back. As noted above, the PCT does not disclose, teach or even suggest instructing a user to place, or placing, a cooling device on any site, let alone at a location on the upper back of the woman, as recited in the present claims.

Moreover, the PCT does not recognize or even suggest the surprising, unexpected combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present invention. The present claims and

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the surprising and unexpected advantages achieved by applicant are unpredictable from the deficient teachings of the PCT.

In summary, the PCT is grossly deficient with respect to the present claims. Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even consider the present methods, let alone do so and expect to obtain the surprising, unexpected and unpredictable combination of advantages achieved only by applicant. Thus, applicant submits that the rejections based in whole or in part on the PCT are not properly based since they are derived from an improper hindsight view of applicant's own disclosure and invention.

In view of the above, applicant submits that the PCT provides no motivation, no other reasonable or rational basis and no common sense basis for making obvious the present invention, and obtaining the surprising, unexpected and unpredictable combination of advantages achieved only by applicant.

Pharmacy Key discloses that a lidocaine transdermal patch is indicated for relief of pain associated with post-herpetic neuralgia. Pharmacy Key discloses that in a study of 15 normal volunteers, three patches placed on the back for 12 hours resulted in mean dose absorbed of 64 mg and produced peak concentrations of 0.13 mcg/mL.

Pharmacy Key does not disclose, teach or suggest the prevent invention. Pharmacy Key has absolutely nothing to do with treating hot flashes. The volunteers tested were normal, rather than women experiencing or anticipating experiencing a hot flash associated with menopause. Pharmacy Key disclosed the use of an analgesic device, not a cooling device. Simply put,

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Pharmacy Key provides no basis whatever for making obvious or even contributing to making obvious the present claims.

Therefore, applicant submits that the present claims, that is claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 68-70, are unobvious from and patentable over the "BeKool Hot Flash" material or pamphlet improperly relied on by the Examiner and/or the PCT, taken alone or in combination with Pharmacy Key, under 35 U.S.C. 103(a).

The other documents cited by the Examiner do not supply the deficiencies apparent in the improperly relied on "BeKool Hot Flash" material or pamphlet.

JP '529 does not disclose, teach or suggest the present invention. For example, JP '529 does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or in a woman anticipating experiencing a hot flash associated with menopause including providing a woman experiencing a hot flash or anticipating experiencing a hot flash with a cooling device in a package having instructions to place a cooling device at a location on her upper back to thereby treat the hot flash (claim 33) or placing a cooling device at a location on the upper back of the woman (claims 55 and 61), as recited in the present claims.

U.S. '899 does not disclose, teach or suggest the present invention. For example, U.S. '899, like JP '529, does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman

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experiencing such a hot flash or in a woman anticipating experiencing a hot flash associated with menopause comprising providing a woman experiencing a hot flash or anticipating experiencing a hot flash with a cooling device in a package having instructions to place the cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

Neither JP '529 nor U.S. '899 recognizes or even suggests the surprising, unexpected and unpredictable combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner, while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved in accordance with the present invention. Both JP '529 and U.S. '899 are deficient with regard to the present claims.

The present specification, at page 2, acknowledges the existence of an adhesive cooling composition shaped into a sheet, and coolers carried in a woman's purse so that when a hot flash occurs, the cooler is removed from her purse and slid onto the woman's wrist.

The prior art coolers acknowledged by applicant do not disclose, teach or even suggest placing the coolers on the upper back of a woman experiencing or anticipating experiencing a hot flash associated with menopause to treat the menopausal hot flash, let alone obtaining the surprising, unexpected and unpredictable combination of advantages, noted above, as achieved by applicant in accordance with the present invention.

To reiterate, applicant submits that the "BeKool" Hot Flash material or pamphlet relied on by the Examiner is not prior art

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against the present claims, and cannot properly be used to render the present claims unpatentable. Moreover, the Examiner has no evidentiary basis for contending that the "BeKool Hot Flash" material or pamphlet relied on as a primary reference by the Examiner is prior art against the above-identified application. To the contrary, the only evidence of record presently by applicant makes clear that this material is not prior art.

Moreover, none of the actual prior art, taken singly or in combination, disclose, teach or even suggest the present claims and the surprising, unexpected and unpredictable combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner while respecting the woman's privacy and allowing the woman to conduct her normal activities, achieved by applicant, and only applicant, in accordance with the present claims.

There simply is no motivation, no other reasonable or rational basis and no common sense basis for one of ordinary skill in the art to combine and extend the deficient teachings of the prior art to make obvious the presently claimed methods and obtain the surprising, unexpected and unpredictable combination of advantages of such methods achieved by, and only by, applicant.

Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art practice the present methods, including instructing a woman experiencing a menopausal hot flash or anticipating experiencing menopausal hot flashes to place, or placing, a cooling device on the upper back of the woman and expect to obtain, let alone obtain the unexpected,

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surprising and unpredictable combination of advantages achieved by applicant and applicant alone.

In view of the above, applicant submits that the present claims, that is claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 and 68-70, are unobvious from and patentable over the prior art, in particular, the improperly relied on "BeKool Hot Flash" material, the PCT, JP '529 and/or U.S. '899 under 35 U.S.C. 102(b) and 103(a).

Applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, the prior art does not disclose, teach or suggest the present apparatus and systems including the addition feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is, claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, and 68-70 satisfy the requirements of 35 U.S.C. 112 and are unobvious from and patentable over the prior art under 35 U.S.C. 103 (a). Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at

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an early date. Should any matters remain unresolved, the Examiner is requested to call applicant's attorney at the telephone number given below.

Respectfully submitted,

A handwritten signature in black ink, reading "Donald E. Stout". The signature is written in a cursive style with a large, stylized "D" at the beginning.

Donald E. Stout

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